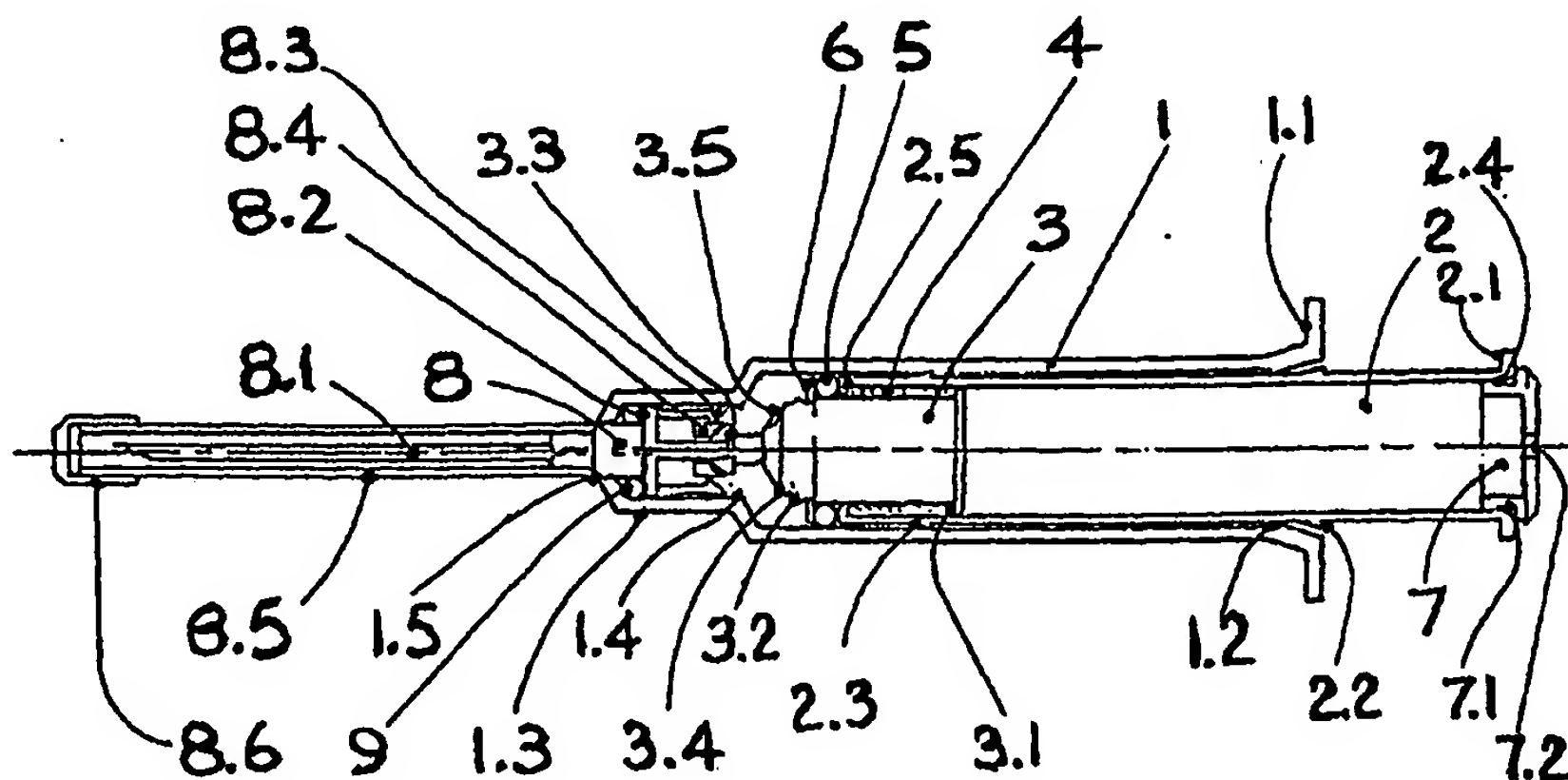




## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

|   |  |   |
|---|--|---|
| (51) International Patent Classification <sup>7</sup> :<br><b>A61M 5/32</b>   | <b>A1</b>  | (11) International Publication Number: <b>WO 00/18454</b><br>(43) International Publication Date: 6 April 2000 (06.04.00) |
| <p>(21) International Application Number: PCT/GB99/03170</p> <p>(22) International Filing Date: 22 September 1999 (22.09.99)</p> <p>(30) Priority Data:<br/>9820784.8 25 September 1998 (25.09.98) GB</p> <p>(71)(72) Applicants and Inventors: PARKER, David, William [GB/GB]; 4 Kimble Close, Greenmount, Bury BL8 4QQ (GB). BURGESS, Colin, Hamilton [GB/GB]; 45 Holcombe Lee, Ramsbottom, Bury BL0 9QR (GB).</p> <p>(74) Agents: READ, Matthew, Charles et al.; Venner, Shipley &amp; Co., 20 Little Britain, London EC1A 7DH (GB).</p> | <p>(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).</p> <p><b>Published</b><br/>With international search report.<br/>Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</p> |   |

(54) Title: IMPROVEMENTS IN OR RELATING TO HYPODERMIC SYRINGES



## (57) Abstract

A disposable hypodermic syringe which is provided with the needle fitted and sheathed and which provides automatic retraction of the needle after use. The syringe may be supplied pre-charged with an injectant. In this invention the completion of the injection stroke attaches the piston (3) to the needle carrier (8) and subsequently dislodges a retaining ring (6) thereby freeing the piston (3) from the plunger (2) and releasing stored energy of the spring (4) to draw the piston (3) and needle carrier (8) into the plunger (2). The plunger (2) is positively retained inside the housing (1) by the interaction of rings (1.2) and (2.2). Alternative methods of locating the needle carrier (8) during use and of attaching the piston (3) to the needle carrier (8) to enable retraction are shown. An alternative method of retaining the piston (3) on the plunger (2) is also shown. A further configuration is shown affording the use of an off-set needle. The syringe has optional features to prevent unwanted inward movement of the plunger (2) and to prevent seepage of liquid after use.

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## **IMPROVEMENTS IN OR RELATING TO HYPODERMIC SYRINGES**

In the often high pressure conditions of medical work, the accidental puncture or scratch with a needle, commonly known as a needlestick injury, and consequent risk of infection with, for example, HIV or hepatitis is becoming increasingly hazardous to the profession and potentially more costly to health authorities.

Detailed statistics of needlestick injuries are not generally published in the UK but in the USA such information is more readily available. In 1994 there were some 800,000 cases reported of which 16,000 involved infection with HIV. It is estimated that in the USA these injuries cost, excluding legal or insurance expenses, \$1.8 billion pa.

The urgent need to address this problem has been widely acknowledged and many relevant designs tabled. For the present invention the requirements for a syringe that will prevent needlestick injuries were analysed and listed as follows.

1. Reliability and ease of use.
2. Automatic and complete retraction of the needle after injection.
3. The capability to retract a needle bent intentionally or accidentally.
4. Re-exposure of the needle is impossible.
5. Suitable for production in larger sizes with an offset needle.
6. Supplied with needle fitted and sheathed.
7. Suitable for supply charged with an injectant.
8. Prevention of accidental needle retraction.
9. Low production costs.
10. Firm and compact for safe disposal.

The preceding criteria have been met in full by the present invention which provides a hypodermic syringe in which:-

The needle can be lockable in both the extended and withdrawn positions.

The resilience of the structural materials of the syringe can be used to provide reversible and non reversible snap action of the components.

The automatic retraction of the needle can be by stored energy.

The principal components referred to in this document are:-

| Reference No. | Component Title       |
|---------------|-----------------------|
| 1.            | Housing               |
| 2.            | Plunger               |
| 3.            | Piston                |
| 4.            | Spring                |
| 5.            | 'O' seal (piston)     |
| 6.            | Retaining ring        |
| 7.            | Plunger closure piece |
| 8.            | Needle carrier        |
| 9.            | 'O' seal (needle)     |
| 10.           | Plunger stop          |
| 11.           | Drip stop             |

The following descriptions and associated drawings are by way of explanation and are not exclusive.

Figure 1 shows a typical construction of the syringe. The cylindrical housing (1), graduated as required, carries a flange (1.1) and the open end of the bore has a tapered entry with a locally reduced diameter forming a wedge section ring (1.2).

At the distal end of the housing the diameter is reduced to form a nose (1.3). An internal lip (1.4) is formed at the point where the nose (1.3) meets the main body of the housing (1). The distal end of the nose (1.3) is partly closed leaving an aperture (1.5).

The plunger (2) has on its outer surface a flange (2.1) and two wedge section rings (2.2) and (2.3).

On the inner surface of the plunger (2) at the flanged end is a tapered entry and a locally reduced diameter forming a wedge section ring (2.4).

At the distal end of the plunger (2) is an inward facing flange (2.5).

The piston (3) has an outward facing flange (3.1). The principal diameter of the piston is reduced locally forming a triangular section ring (3.2). The closed end of the piston terminates in a head (3.3). The shoulder (3.4) of the piston is grooved to form a fluid bypass (3.5).

The spring (4) is held in compression between flanges (2.5) and (3.1).

The 'O' seal (5) is held between the retaining ring (6) and the flange (2.5). The retaining ring (6) is dislodgeably held in place by the triangular section ring (3.2).

The plunger closure piece (7) has a locally reduced diameter (7.1) and is irreversibly retained by the wedge section ring (2.4) of the plunger (2). An orifice (7.2) is provided in the plunger closure piece.

The needle carrier (8) incorporates a needle (8.1) and a flange (8.2) on which are claw ended arms (8.3). The inwardly sprung arms (8.3) are held in engagement with the lip (1.4) by a spring ring (8.4).

The 'O' seal (9) is located and held in place by the flange (8.2).

The needle protective sheath (8.5) is mounted on the needle carrier (8) and is of a lesser diameter than the aperture (1.5). The end cap (8.6) fits over the needle protective sheath (8.5) to form an air-tight seal and is of a larger diameter than the aperture (1.5).

Figures 3, 4 and 5 show alternative constructions of the needle retention and pick up means.

Figure 3 shows a needle carrier (8) which has a cup (8.7) displaced from the centre line and lodged behind the lip (1.4). The open end of the cup has a retaining lip (8.8). An 'O' seal (9.1) is located in the needle carrier (8). The piston (3) has a fluid bypass (3.5). The piston head (3.3) has a fluid passage (3.6).

Figure 4 shows a needle carrier (8) in which the cup (8.7) is in firm ring contact with the cylindrical portion of the nose (1.3). No separate seal is used. The closed end of the cup is dished (8.9). The open end of the cup has a retaining lip (8.8). The piston (3) has a fluid bypass (3.5). The piston head (3.3) has a fluid passage (3.6).

Figure 5 shows a needle carrier (8) with outwardly sprung arms (8.10). The arms have claw ends (8.11) and catches (8.12) that engage with an internal lip (1.6). A flange (8.13) abuts an internal shoulder (1.7) of the nose (1.3). An 'O' seal (9.1) is located in the needle carrier. The piston (3) has a cup end (3.7) with an inwardly facing lip (3.8) and a fluid passage (3.9).

Figure 6 shows a construction with an alternative co-action between the plunger (2) and the piston (3). The plunger (2) provides a sealing surface (2.6) and a face (2.7) that locates the spring (4). The plunger head (2.8) has an inward facing lip (2.9) which lodges against the triangular section ring (3.2).

Figure 7 shows a typical construction in which the needle (8.1) is offset from the centre line. The housing (1) has a nose (1.3) of reduced diameter with an aperture (1.5) through the end wall.

The needle carrier (8) has the needle (8.1) eccentrically positioned and aligned with the aperture (1.5). The flange (8.14) has a reduced diameter which carries the 'O' seal ring (9.2) and the claw ended arms (8.3) which are held in engagement with the lip (1.4) by a spring ring (8.15) which has a recess (8.16) and one or more cut-outs (8.17).

The piston (3) has a triangular section annular ridge (3.2) on the outer cylindrical surface. The piston (3) terminates in a head (3.3).

A sprung anchor (3.10) is fitted inside the piston (3). A separate anchor (7.3) is attached to the plunger closure piece. (7). The spring (4.1) is attached at both ends to the anchors (3.10) and (7.3).

The plunger has a sealing surface (2.6) and the plunger head (2.8) has an inward facing lip (2.9). The inward lip (2.9) lodges against the triangular section annular ridge (3.2) thereby holding the spring (4.1) in tension.

Figure 8 shows a plunger stop (10) with suitably radiused members (10.1) to fit over the exposed length of the plunger (2) between the flanges (1.1) and (2.1) as shown in figure 1. The length of the stop will be dependent upon whether it is being used to prevent accidental needle retraction before use or to prevent accidental discharge of pre-loaded injectant. The members are capable of having a label (10.2) affixed.

Figure 9 shows an anti-drip cap (11) designed to fit over the syringe nose (1.3) (shown in figure 1). The substantially flat end is split to form segments (11.1) which are flexible to allow the passage of the needle sheath (8.5) (shown in figure 1) during assembly and also to re-close after needle retraction. A similar cap may be provided un-segmented when capping after needle retraction is required.

Operation of the syringe follows the established practice for disposable syringes. When the operator is charging the syringe, over extension of the plunger (2) is prevented by the interaction of the rings (1.2) and (2.3). On completion of the injection stroke, automatic needle retraction is triggered by continued pressure on the plunger. Description of this operation follows and is with reference to figures 1 and 2.

When the piston shoulder (3.4) meets the end wall of the housing (1), the piston head (3.3) has entered between the clawed arms (8.3) of the needle carrier (8) and displaced the spring ring (8.4), allowing the clawed arms (8.3) to snap onto the piston head (3.3) providing positive attachment with some angular freedom to ensure positive needle retraction. The fluid bypass (3.5) ensures freedom from fluid lock.

Further pressure on the plunger (2) against the now stationary piston (3), dislodges the retaining ring (6), freeing the spring (4) to snap the needle carrier (8) into the plunger (2) and to retain it therein.



Figure 2 shows the syringe after needle retraction. As shown, the 'O' seals (9) and (5) and the retaining ring (6) remain at the nose end (1.3) of the housing (1), ensuring minimum friction during needle retraction. Release path for air is afforded by the plunger closure piece orifice (7.2). During the injection stroke the wedge section ring (2.2) snaps past the co-acting wedge ring (1.2) thereby preventing re-extension of the plunger.

The optional un-segmented end cap is, if required, now fitted over the nose (1.3)

Operation of a syringe containing an alternative construction of the needle carrier as described with reference to figures 3, 4 and 5, is essentially as outlined with reference to figures 1 and 2.

Figure 3 shows a revised needle carrier (8) of resilient material with a cup (8.7) displaced from the centre line of the syringe so as to latch behind the lip (1.4) during assembly. Near the end of the injection stroke the piston head (3.3) centralises the cup (8.7) which snaps behind the retaining lip (8.8) disengaging the cup (8.7) from the lip (1.4). The fluid by pass (3.5) and the fluid passage (3.6) ensure freedom from fluid lock. Needle retraction follows the sequence described with reference to figures 1 and 2 except that the needle seal (9.1) remains in the needle carrier (8).

Figure 4 shows a needle carrier (8) of resilient material with a cup (8.7) in firm ring contact with the cylindrical section of the nose (1.3) obviating the need for a seal. During operation any end load on the needle tends to flatten the dished area (8.9) increasing the radial load against the cylindrical portion of the nose (1.3), preventing axial movement and making additional locking unnecessary. At the end of the injection stroke, when the piston head (3.3) enters the cup (8.7) it is retained by the lip (8.8). Subsequent pull on the cup during needle retraction tends to elongate the cup, reducing its radial pressure against the nose (1.3) allowing free movement. The fluid by pass (3.5) and the fluid passage (3.6) ensure freedom from fluid lock. Needle retraction follows the sequence as described with reference to figures 1 and 2 except for the absence of the 'O' seal (9).

Figure 5 shows a needle carrier (8) with outwardly sprung arms (8.10) with catches (8.12) such that on insertion into the housing (1), the catches (8.12) snap behind the lip (1.6) to lock the needle carrier (8) in position.

Towards the end of the injection stroke the piston cup end (3.7) passes over claw ends (8.11) closing the arms (8.10) and disengaging the catches (8.12) from the lip (1.6) and connecting the claw ends (8.11) to the lip (3.8) of the piston cup end (3.7). The fluid passage (3.9) ensures freedom from fluid lock. Needle retraction follows the sequence described with reference to figures 1 and 2 except that the seal (9.1) is retained in the needle carrier (8).

Figure 6 depicts an alternative construction of the plunger seal and the dislodgeable retaining means for the piston.

In this construction the plunger (2) has a head (2.8) of sufficient resilience to effect a dynamic seal (2.6) against the inner surface of the housing (1). The head (2.8) has an inward facing lip (2.9) which co-acts with triangular section ring (3.2) of the piston (3) to effect a seal between the plunger (2) and the piston (3).

The spring (4) is compressed and retained between faces (2.7) and (3.1) by the reversible snap co-action of the triangular section ring (3.2) and the inward facing lip (2.9) of the plunger (2.). At the completion of the injection stroke the inward facing lip (2.9) snaps past the triangular section ring (3.2) releasing the spring to effect needle retraction.

Needle retraction follows the sequence described with reference to figures 1 and 2 except for the absence of the 'O' seal (5).

Figure 7 shows an adaptation of the invention in which the needle is offset from the centre line of the syringe in order to meet the operational requirements of larger capacity syringes.

To allow the maximum eccentricity of the needle (8.1), extra space has been obtained by replacing the compression spring of the standard models with a tension spring (4.1).

Operation follows the usual procedure. Towards the end of the injection stroke the piston head (3.3) displaces the spring ring (8.15), allowing the claw ended arms (8.3) to snap onto the piston head (3.3).

To ensure continuous free fluid flow the spring ring (8.15) is recessed at (8.16) and cut away at one or more points (8.17).

When the piston (3) bottoms at the end of the stroke, continued pressure on the plunger (2) causes the inward facing lip (2.9) to override the triangular section ring (3.2), allowing the spring (4.1) to effect needle retraction.

Needle retraction generally follows the sequence as described with reference to figures 1 and 2.



**CLAIMS**

1. A hypodermic syringe including a housing, a plunger located in the housing, a needle carrier with a needle mounted on the carrier and stored energy means; operation of the plunger causing the plunger to be attached to the needle carrier and to release the energy stored in the stored energy means in order to retract the needle carrier.
2. A syringe as claimed in claim 1 in which the plunger comprises a casing and a piston located and movable within the casing.
3. A syringe as claimed in claim 1 or claim 2 in which the stored energy means comprises a spring co-operating between the piston and the casing and having a releasable retaining means in order to release the energy stored within the spring.
4. A syringe as claimed in claim 3 in which the releasable retaining means comprises a ring located on the piston and displaceable by relative movement between the casing and the piston.
5. A syringe as claimed in claim 3 in which the releasable retaining means comprises a sprung lip on the casing engaging with a circular ridge formed on the piston.
6. A syringe as claimed in any one of the preceding claims 3, 4 or 5 in which the spring is a tension or compression spring.
7. A syringe as claimed in any one of the preceding claims 2 to 6 in which the piston includes means for engagement with the needle carrier.

8. A syringe as claimed in claim 7 in which the engagement means comprises either a male or a female member on the head engaging with a corresponding male or female member on the needle carrier.
9. A syringe as claimed in claim 8 in which the engagement means comprises a projection formed on the piston and the needle carrier comprises a number of spring biased arms which are retained in position by a collar, the collar being displaceable by the projection on the head such that the arms engage behind the projection thereby attaching the needle carrier to the piston.
10. A syringe as claimed in claim 7 in which the needle carrier includes a cup which is retained in position by a lip formed on the housing and a projection on the piston is engageable with the cup so as to release the cup from engagement with the lip and the cup has a lip which engages behind the projection thereby joining the needle carrier to the piston.
11. A syringe as claimed in claim 7 in which the needle carrier includes a number of deflectable arms which are engageable with an opening in the piston so as to join the needle carrier with the piston.
12. A syringe as claimed in claim 11 in which the needle carrier has at least one projection engaging with a lip to retain the needle carrier to the housing of the syringe prior to displacement of the deflectable arms, displacement of the deflectable arms releasing the needle carrier from the housing.
13. A syringe as claimed in any one of the preceding claims 7 to 12 in which the means of engagement between the piston and the needle carrier includes a fluid passage to prevent fluid lock.

14. A syringe as claimed in any one of the preceding claims in which the plunger and the housing are formed with means for engaging one another so as to prevent removal of the plunger from the casing.

15. A syringe as claimed in claim 14 in which the plunger is provided with at least one projection which is engageable with a corresponding lip on the housing.

16. A syringe as claimed in any one of the preceding claims including a sheath for the needle.

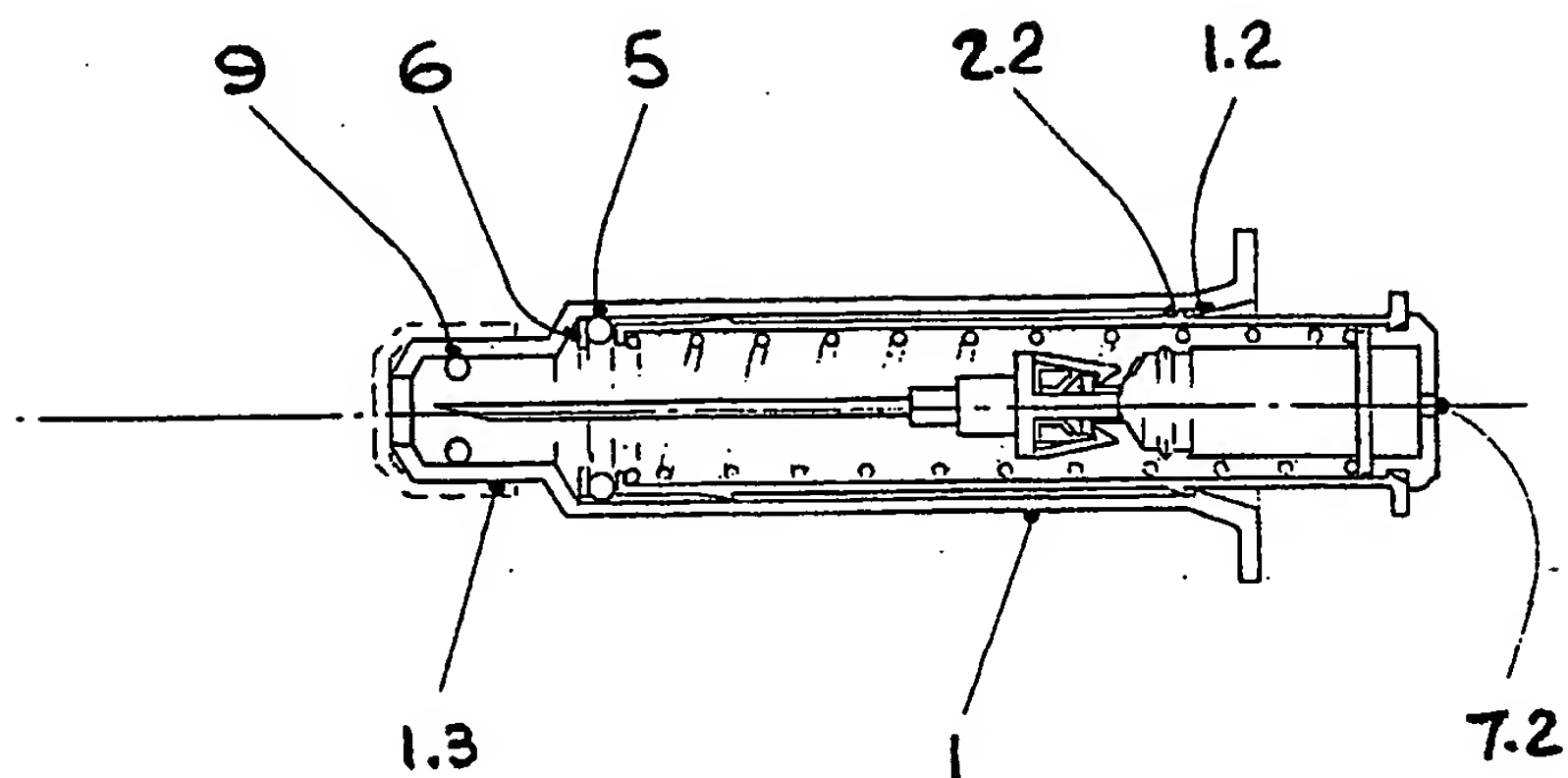
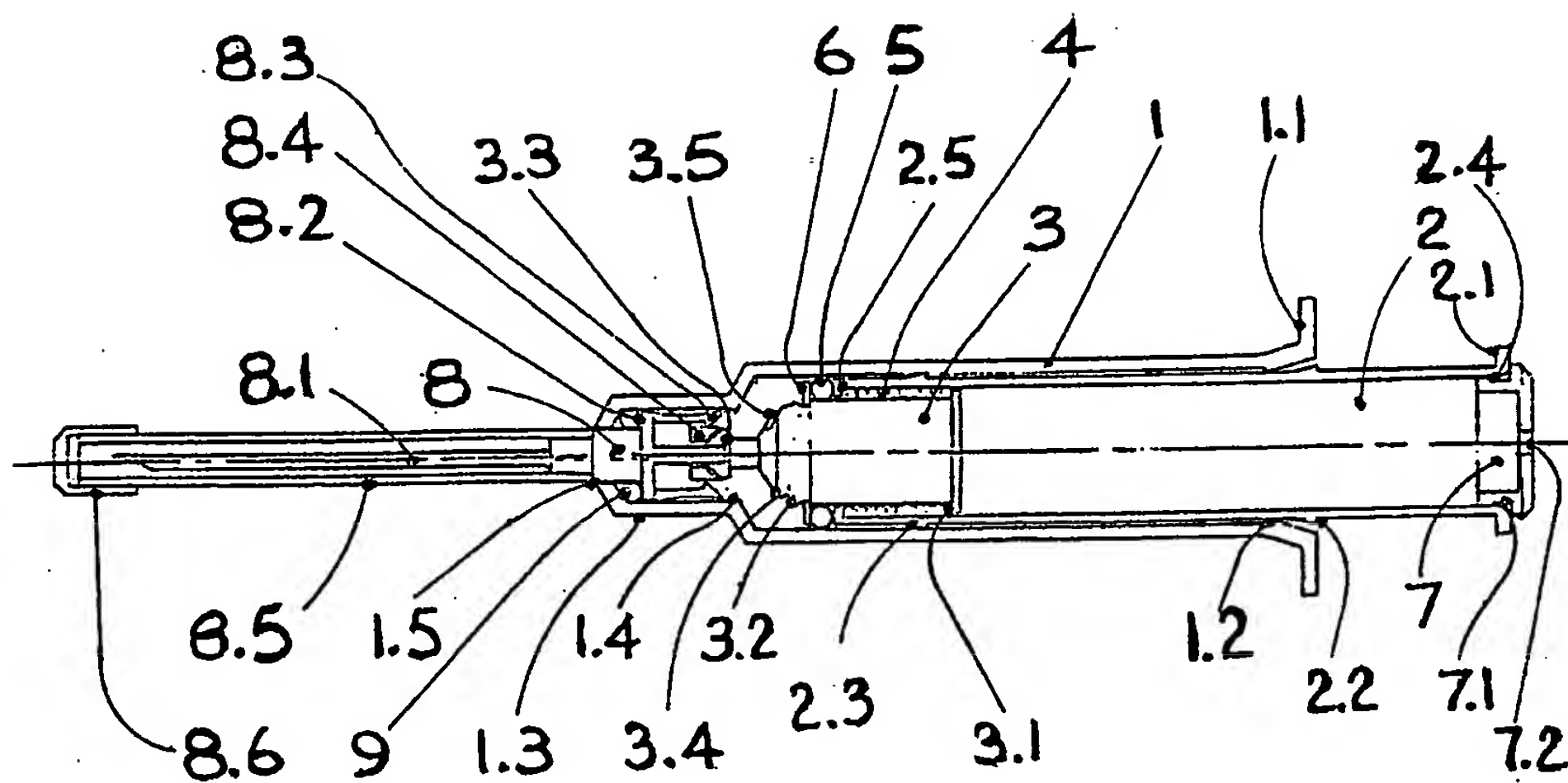
17. A syringe as claimed in claim 16 in which the sheath is provided with a cap.

18. A syringe as claimed in any one of the preceding claims in which the housing is provided with a penetrable and self-closing cap to prevent fluid seepage.

19. A syringe as claimed in any one of the preceding claims in which the needle axis is displaced from the centre line of the barrel.

20. A syringe as claimed in any one of the preceding claims in which a detachable spacer capable of being labelled is located between the open end of the housing and the flanged end of the plunger so as to inhibit unwanted inward movement of the plunger.

21. A hypodermic syringe constructed and arranged for use and operation substantially as herein described and with reference to the accompanying drawings.



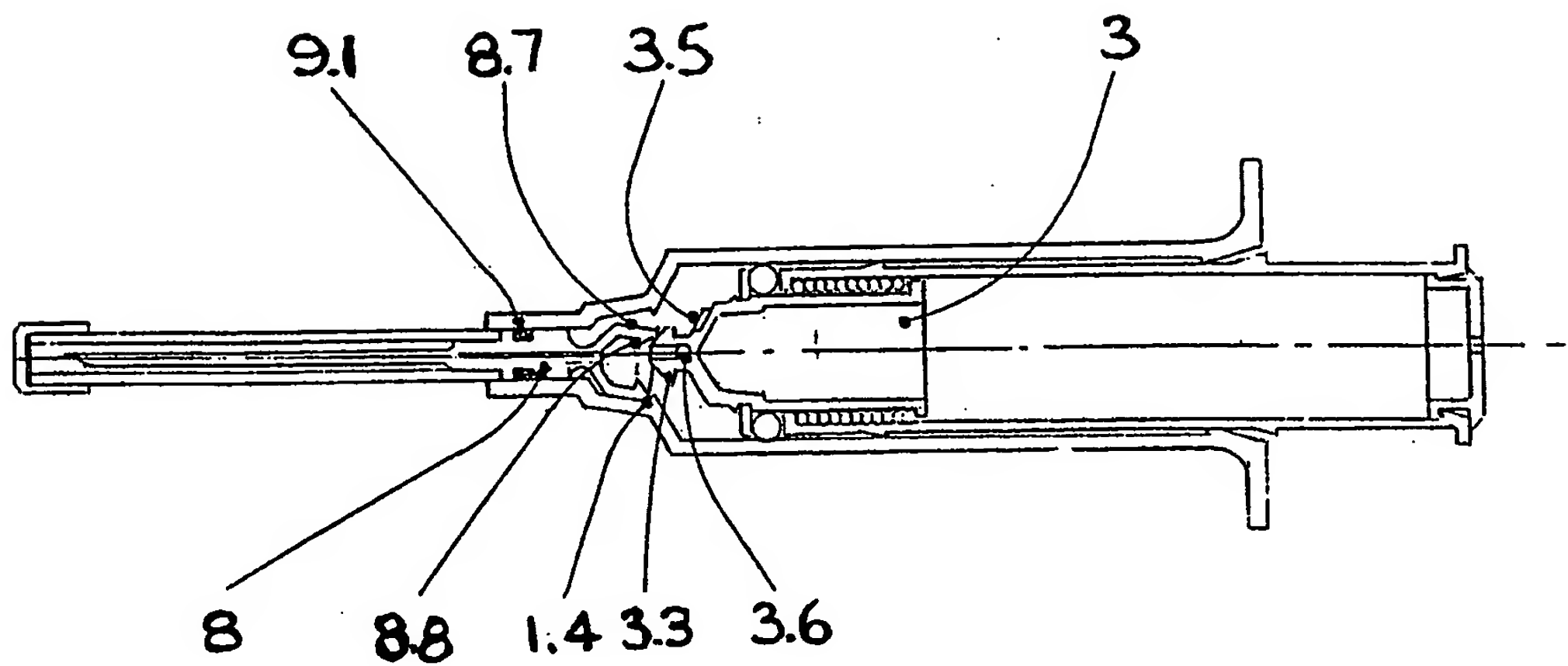


FIG. 3

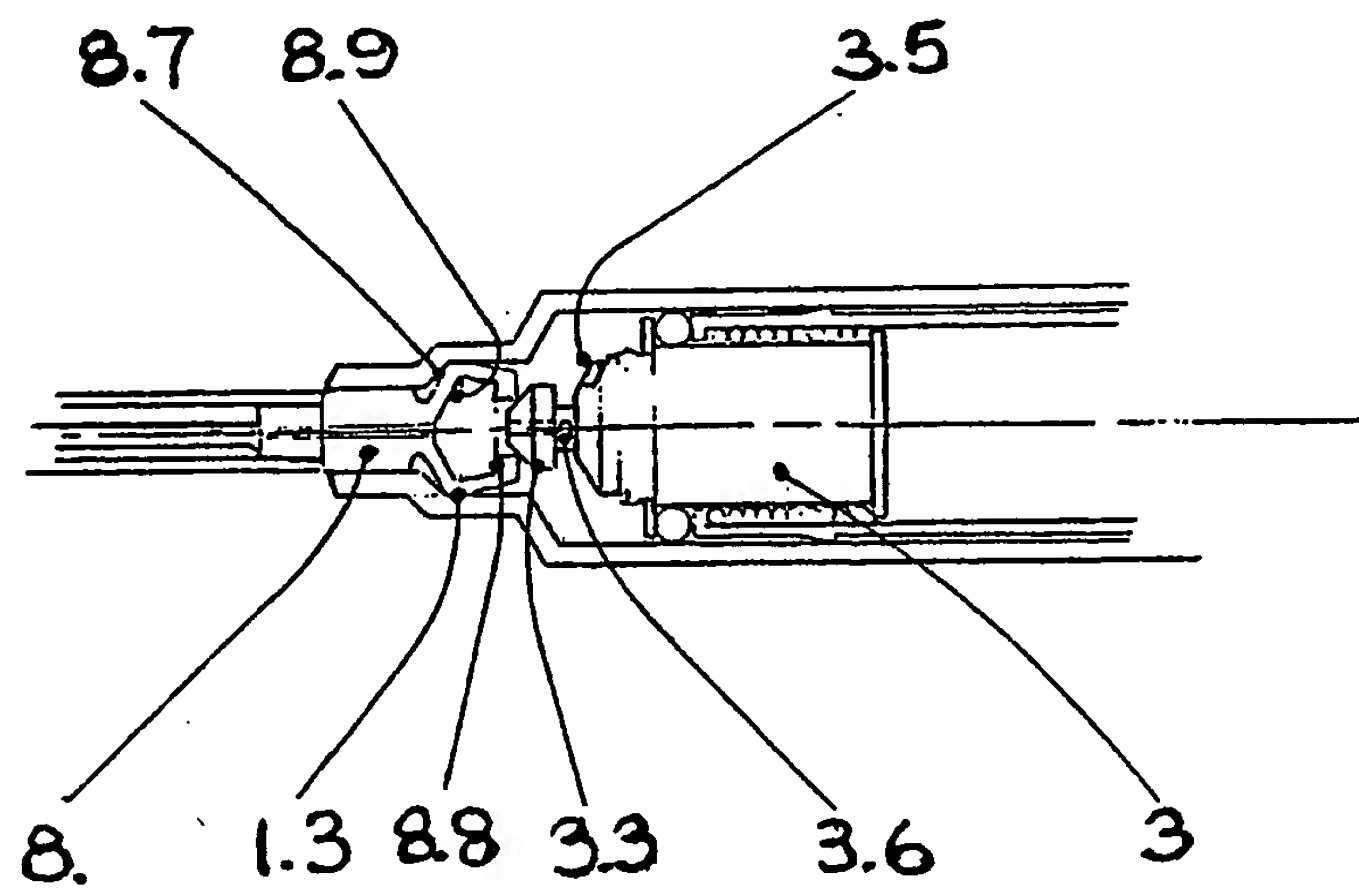


FIG. 4





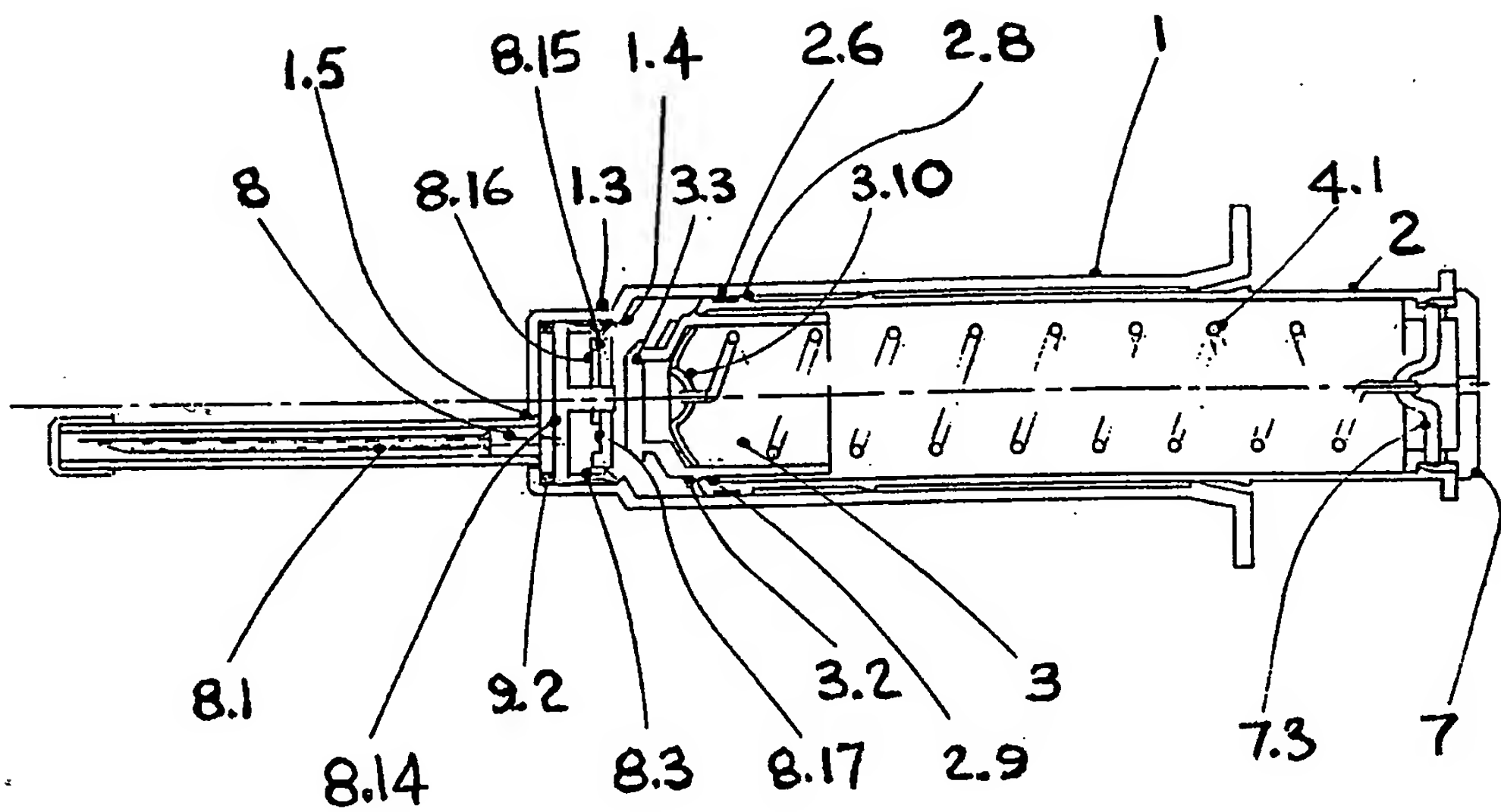


FIG. 7

FIG. 8

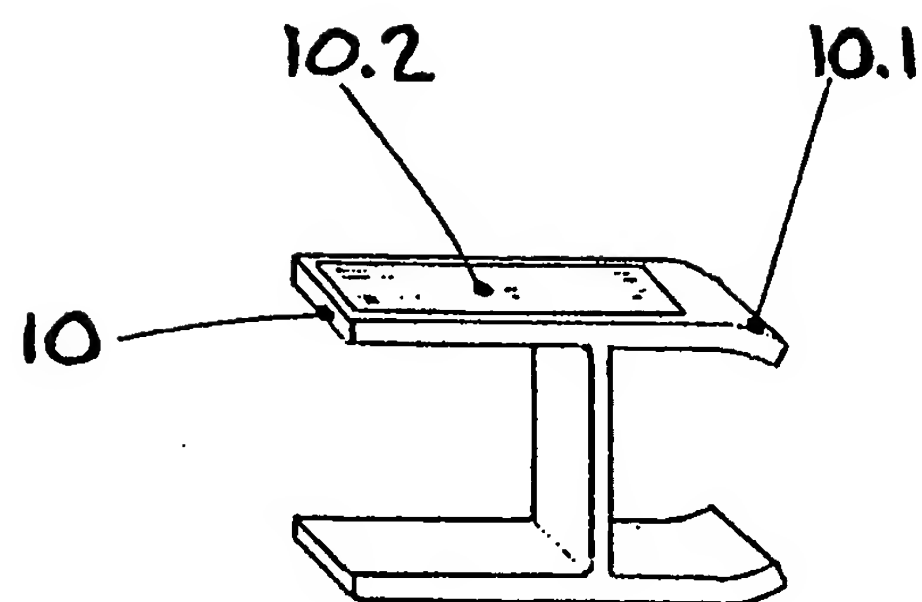
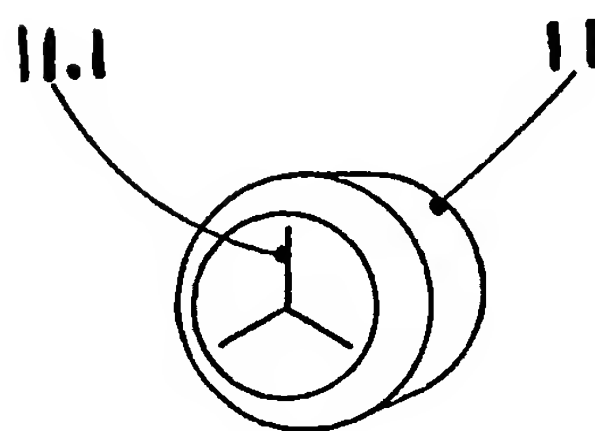


FIG 9



# INTERNATIONAL SEARCH REPORT

Inte Jonal Application No

PCT/GB 99/03170

## A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61M5/32

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category ° | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|------------|--|-----------------------|
| X          | US 5 211 628 A (MARSHALL JOHN M)<br>18 May 1993 (1993-05-18)                       | 1-3,6-8               |
| A          | the whole document   | 5,11,12               |
| X          | US 5 324 265 A (MURRAY KENNETH W ET AL)<br>28 June 1994 (1994-06-28)               | 1-3,6-8,<br>14        |
| A          | the whole document   | 9                     |
| X          | EP 0 505 330 A (PROFARM SPA)<br>23 September 1992 (1992-09-23)                     | 1-3,5,8               |
| A          | the whole document   | 9                     |
| X          | WO 91 03269 A (TOWNSEND CONTROLS PTY LTD)<br>21 March 1991 (1991-03-21)            | 1-3,6,<br>11,12       |
|            | the whole document   |                       |

-/--



Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

° Special categories of cited documents :

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Date of the actual completion of the international search

11 January 2000

Date of mailing of the international search report

25/01/2000

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Jameson, P

# INTERNATIONAL SEARCH REPORT

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## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

| Category * | Citation of document, with indication, where appropriate, of the relevant passages            | Relevant to claim No. |
|------------|---|-----------------------|
| X          | US 5 114 404 A (SEID NORMAN W ET AL)<br>19 May 1992 (1992-05-19)<br>abstract; figure 2<br>--- | 1,20                  |
| X          | WO 93 07923 A (KAUFHOLD HARRY JR)<br>29 April 1993 (1993-04-29)<br>abstract; figure 2<br>---  | 1,2                   |
| A          | US 5 344 403 A (LEE RAHNFONG)<br>6 September 1994 (1994-09-06)<br>abstract; figure 6<br>----- | 19                    |

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/GB 99/03170

### Box I Observations where certain claims were found unsearchable (Continuation of Item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:  
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☒ Claims Nos.: 21  
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:  
PCT Rule 6.2(a)
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

### Box II Observations where unity of invention is lacking (Continuation of Item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.2

Claims Nos.: 21

P.C.T. Rule 6.2(a)

The applicant's attention is drawn to the fact that claims, or parts of claims, relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure.



# INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/GB 99/03170

| Patent document<br>cited in search report | Publication<br>date | Patent family<br>member(s)   | Publication<br>date  |
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